Docket No.: ECV-5631

BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Diana Nguyen-Thien-Nhon, et al.) Group Art Unit: 3738
)
Application No.: 09/745,386) Examiner: A. Stewart
)
Filing Date: December 21, 2000)
)
For: HEART VALVE HOLDER THAT RESISTS SUTURE)
LOOPING)

REVISED APPEAL BRIEF

Commissioner for Patents
BOX AF
Washington, DC 20231

Dear Sir:

This is an appeal from the final rejections of claims 1-4 and 24-25 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,865,600 to Carpentier, et al. For the reasons discussed below, Applicants request reversal of the rejection and allowance of the claims. The Notice of Appeal is filed concurrently, making this Appeal Brief timely.

I.

REAL PARTY IN INTEREST

The real party in interest is Edwards Lifesciences Corporation as indicated by an Assignment of the present application from the inventors recorded at Reel 011698, Frames 0811-0815.

II.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III.

STATUS OF THE CLAIMS

Claims 1-4 and 24-25 are pending and appear in attached Appendix A. Claims 5-7 and 26 also appear in Appendix A, though they are withdrawn as being drawn to non-elected Species II. Currently, claim 1 is generic to Species I and II, and thus claims 5-7 and 26 should be allowed if and when claim 1 is allowed in generic form.

IV.

STATUS OF AMENDMENTS

An Amendment After Final under 37 C.F.R. §1.116 was filed on August 29, 2002 containing no claim amendments. That amendment was considered but not entered by the Examiner as indicated in an Advisory Action dated September 12, 2002 because the arguments did not allegedly materially reduce or simplify issues for appeal.

A second Amendment After Final under 37 C.F.R. §1.116 is submitted concurrently herewith. This amendment makes minor changes to claim 24 and introduces a Declaration of Diana Nguyen under 37 C.F.R. §1.132 in support of the following arguments.

V.

SUMMARY OF THE INVENTION

The invention as claimed pertains to an improved holder for implanting a tissue-type prosthetic mitral heart valve that prevents suture looping. With reference to Fig. 1, and to the specification page 7, line 5 through page 8, line 13, the holder includes two relatively movable plates 40 and 44, one (40) of which attaches to the valve sewing ring 24 on the inflow end of the valve 22. The other plate 44 attaches via flexible lengths of material 60, 70, 80, 102 (e.g., sutures) to the valve commissure posts 26 on the outflow end of the valve 22 (see, e.g., Fig. 1 and text page 8, lines 14-31). Separation of the plates places the sutures in tension and radially constricts the flexible commissure posts (see, e.g., text page 9, lines 1-12), which is desired when implanting the mitral valve outflow end first. The flexible lengths of material extend directly between the valve commissure post tips, and a barrier to suture looping is created by crossing the flexible lengths of material over just radially inward from the commissure post tips (see, e.g., Figs. 2 and 3, and text page 10, lines 3-15). Specifically, each length of material has a first segment 61 extending directly between adjacent commissure posts and crossing over (i.e., intersecting) each adjacent length of material just radially inward from the commissure post 26 therebetween (see text page 10, lines 3-15). With reference to Figs. 1-10, the flexible lengths of material may be strands or filaments, or may be wider bands of flexible biocompatible material.

If bands are used, they desirably cover the commissure post tips to further help prevent suture looping thereover (see, e.g., Figs. 4 and 5, and text page 11, lines 20-25).

VI.

ISSUES

I) Whether claims 1-4 and 24-25 are not patentable under 35 U.S.C §103(a) as being obvious over U.S. Patent No. 4,865,600 to Carpentier, et al.

VII.

GROUPING OF CLAIMS

Claims 2-4 and 24-25 depend from and stand or fall together with independent claim 1.

VIII.

ARGUMENT

There is only one type of rejection of the claims.

Claims 1-4, 24, and 25 stand rejected under 35 U.S.C. section 103(a) as being obvious in view of U.S. Patent No. 4,865,600 to Carpentier, et al.

Carpentier, et al. do not teach the claimed configuration. Specifically, as seen clearly at the bottom of Fig. 8 in Carpentier, et al., the lengths of suture diverge in opposite directions at the commissure tips rather than crossing over.

The examiner argues that: a) it would have been an obvious design choice to provide the crossed-over suture arrangement as claimed, b) the applicant has not disclosed that the crossing over of the sutures provides an advantage, is used for a particular purpose, or solves a stated problem, and c) one of skill in the art would expect the invention to perform equally well with the sutures not crossing each other.

Initially, it should be noted that the claims at issue specify a plurality of lengths of flexible material that cross over the outflow end of the valve to prevent suture looping. The lengths of flexible material could be sutures or other structures. For the purpose of argument

only, however, these lengths of flexible material will be referred to as sutures herein.

With regard to the first contention, the most obvious arrangement of sutures is not to cross them over to avoid adding complexity in the design. Indeed, the assignee of the present invention also developed the Carpentier, et al. device and has been selling it as it is for many years without change. The present invention is an improvement over the Carpentier, et al. device, and required a significant amount of design work. To summarily conclude that the claimed arrangement is a matter of design choice is to ignore this significant effort, and also to ignore the amount of time that passed (more than ten years) between the Carpentier, et al. invention and the instant invention.

The statement that the present application does not identify that the crossed-over sutures solve any particular problem, etc., is clearly refuted by the specification. First, on page 2 of the present application, the Carpentier, et al. patent is described and problems of suture looping around one of the cloth-covered commissure posts is identified. The next sentence at the bottom of page 2 indicates that an improved design is needed that even better resists suture looping. Furthermore, from page 9, line 18, to page 10, line 15, the arrangement of the crossed-over sutures is provided, and at the end is characterized as providing a plane or slide (a "barrier of sorts") that helps present suture looping. Therefore, the present invention provides an advantage over the Carpentier, et al. design, was intended to be in improvement, and solves the problem by reducing the chance of suture looping.

Finally, the presumption that the present invention would work equally well without the claimed suture cross-over has no basis in any published source, nor for that matter in common knowledge. Indeed, applicants have studied this problem and designed the improvement as claimed herein specifically because it works better. It is logical that the chance of suture looping is reduced by providing more of a barrier at the commissure tips, specifically by crossing over the sutures to provide a plane or slide. Any bare allegation otherwise does not carry weight.

The Appeal Board is urged to consider the attached Amendment After Final which introduces the Declaration of Diana Nguyen under 37 C.F.R. §1.132 in support of these arguments.

IX.

APPENDED CLAIMS

Claims 1-7 and 24-26 pending at the time of the Final Office Action are attached hereto as Appendix A.

Respectfully submitted,

Date: February 14, 2003

Guy Cumberbatch, Reg. No. 36,114
c/o Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6807
Facsimile: (949) 250-6850
Customer No.: 30452

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APPENDIX A

1. A holder for a tissue-type prosthetic heart valve attachable to a surgical delivery handle, the heart valve having an inflow end and an outflow end and a flow axis therebetween, the valve including an annular suture ring at the inflow end and a plurality of generally axially-extending commissure posts circumferentially-spaced around the outflow end that support occluding tissue surfaces of the valve, the holder comprising:

a plurality of lengths of flexible material extending in a taut fashion across the outflow end of the valve to prevent suture looping, each length of material having a first segment extending directly between adjacent commissure posts and crossing over (i.e., intersecting) each adjacent length of material just radially inward from the commissure post therebetween.

2. The holder of claim 1, wherein the lengths of flexible material comprise lengths of suture.

3. The holder of claim 1, the holder further including a rigid structure that abuts the annular sewing ring at the inflow end of the valve, the lengths of flexible material each axially extending in second segments along two adjacent commissure posts and attaching to the rigid structure at two points such that each length may be severed close to one of its points of attachment to the rigid structure and pulled free of the valve along with the rigid structure by virtue of its remaining attachment point.

4. The holder of claim 3, wherein the rigid structure includes a mechanism for pulling the second segments toward the rigid structure causing the first segments to shorten and the commissure posts to flex inward toward each other.

5. The holder of claim 1, wherein the first segment of each length of flexible material comprises a band that is substantially wider than it is thick.

6. The holder of claim 5, the holder further including a rigid structure that abuts the annular sewing ring at the inflow end of the valve, the three lengths of flexible material each axially extending in second segments along two adjacent commissure posts and attaching to the rigid structure at two points such that each length may be severed close to one of its points of attachment to the rigid structure and pulled free of the valve along with the rigid structure by virtue of its remaining attachment point.

7. The holder of claim 6, wherein the commissure posts are cloth covered, and wherein the second segments pass beneath the cloth covering of the respective commissure posts, the second segments having a configuration that is not as wide as the first segments.

24. The holder of claim 1, wherein the lengths of flexible material each axially extending in second segments along two adjacent commissure posts and attach to a structure that abuts the annular sewing ring at the inflow end of the valve, wherein the second segments of two adjacent lengths of flexible material cross over a second time along the common commissure post prior to attaching to the structure.

25. The holder of claim 24, wherein each length of flexible material attaches to the rigid structure at two points such that each length may be severed close to one of its points of attachment to the rigid structure and pulled free of the valve along with the rigid structure by virtue of its remaining attachment point.

26. The holder of claim 5, wherein the band is TEFLON.